



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/976,560 11/24/97 FREIMER

N UCAL-250-020

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EXAMINER

ARTHUR, L

ART UNIT PAPER NUMBER

1655

DATE MAILED: 10/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.

08/976,560

Applicant(s)

FREIMER ET AL.

Examiner

Lisa B. Arthur

Art Unit

1655

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 October 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 18 October 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): rejection under 35 U.S.C. 112, SECOND PARAGRAPH.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: SEE ATTACHMENT.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: NONE.
- Claim(s) objected to: NONE.
- Claim(s) rejected: 1-12, 25-27.
- Claim(s) withdrawn from consideration: _____
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other:

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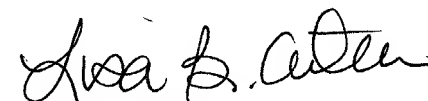
The rejection of the claims made under 35 U.S.C. 112, first paragraph, for scope of enablement and for lack of description are maintained for the reasons of record. The amendment to include the limitation that the polymorphisms are "associated with BP" does not overcome the rejection because the specification and the Declaration do not teach a representative number of polymorphisms that are associated with bipolar disease. Again, the claims are drawn to a research project, i.e. searching for polymorphisms which are associated with BP within the claimed chromosomal region. The Declaration of Dr. McInnes has been thoroughly reviewed and while presenting data that supports the linkage of some markers within the region of chromosome 18 p between SAVA5 and ga203 (a region of around 3 cM) does not support the claimed method of detecting susceptibility to BP by detecting polymorphisms in the region which are associated with BP because neither the specification nor the Declaration teach a representative number of such polymorphisms in this region associated with BP. The specification, Declaration and art do not teach the nature of the linkage between the claimed region and BP, i.e. such a mutated gene or merely a linked sequence, thus making the association particular polymorphisms in this region with BP highly unpredictable. The skilled artisan would be required to analyze each identified polymorphic sequence for possible linkage to BP without a reasonable expectation of whether or not a given polymorphism will be associated or a reliable test to determine whether or not the polymorphism is predictive of risk for BP. Therefore, the rejections are maintained.

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The rejection of the claims made under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's arguments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa B. Arthur whose telephone number is 308-3988. The examiner can normally be reached on Monday-Wednesday from 7:00 am to 2:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196



LISA B. ARTHUR
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

October 24, 2001